

Initial REMS Approved: 05/2015
Most recent modification: 01/2016

ANDA 200652

Alosetron Tablets

Selective 5-HT₃ antagonist

Roxane Laboratories, Inc.
1809 Wilson Road
Columbus, OH 43228
Phone: (614) 276-4000

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL(S):

The goals and objectives of the Alosetron REMS Program are to mitigate the risks of ischemic colitis (IC) and serious complications of constipation (CoC) associated with alosetron hydrochloride (hereinafter, referred to as alosetron) by:

- Informing prescribers of alosetron about:
 - the serious risks of IC and serious CoC associated with alosetron
 - the importance of understanding that alosetron should only be used in severely affected diarrhea-predominant irritable bowel syndrome patients for whom the benefits exceed the risks.
 - the importance of counseling patients about the risks of IC and serious CoC
- Informing patients about the risks of IC and CoC and actions to take should they experience early warning signs and symptoms of these risks.

II. REMS ELEMENTS:

A. Elements to Assure Safe Use

1. Training will be provided to healthcare providers who prescribe alosetron.

- a. Roxane Laboratories (Roxane) will ensure that training provided to healthcare providers who prescribe alosetron includes information on the serious risks of IC and CoC associated with alosetron, the importance of understanding that alosetron should only be used in severely affected diarrhea-predominant irritable bowel syndrome patients for whom the benefits exceed the risks, and the importance of counseling patients about the risks of IC and serious CoC, using the Alosetron Prescribing Information and the following materials in the REMS Training Kit:

- i. REMS letter to Healthcare Providers
- ii. Alosetron REMS Program Prescriber Education Slide Deck
- iii. Alosetron REMS Program Safety Information Fact Sheet for Prescribers
- iv. Alosetron REMS Program Patient Education Sheet
- v. Prescriber Completion of Alosetron REMS Program Training Form

- b. In order to facilitate training, Roxane will:

- i. Ensure that training is provided to healthcare providers who prescribe alosetron by mailing or emailing the REMS Training Kit to healthcare providers who are likely to prescribe, or have prescribed alosetron in the 24 months preceding the REMS modification approval (01/2016). The REMS Training Kit will be distributed within 60 days after approval of the modified Alosetron REMS Program. Likely prescribers include, but are not limited to, general practitioners, family practitioners, internists, gastroenterologists, and nurse practitioners/physician assistants.
- ii. Send a REMS letter for Professional Societies to the following professional societies and organizations, requesting that the letter or the content be provided to their membership within 6 and 12 months after approval of the modified Alosetron REMS Program.

American Academy of Family Physicians
American Academy of Nurse Practitioners
American Academy of Physicians Assistants
American College of Gastroenterology
American College of Physicians
American Gastroenterological Association
American Medical Association

- iii. Ensure that prescribers can notify Roxane when they have completed training via the Alosetron REMS Program website or by faxing or mailing a Prescriber Completion of Training Form.
- iv. Provide acknowledgement of completion of training electronically or by mail to prescribers upon receiving notification that training was completed.
- v. Make REMS Training Materials available at professional society meetings and at medical educational venues where Roxane has a presence.
- vi. Maintain an Alosetron REMS Program website [www.AlosetronREMS.com] and contact center (1-844-267-8675) to support prescribers.
- vii. Monitor distribution and prescription data monthly. Contact all prescribers identified as not having completed training and provide training within 30 days of identification. Contact and provide training to all prescribers who do not report completion of training after the first contact up to two additional times, or until the prescriber reports completion, within 180 days of being first identified.
- viii. Maintain a validated, secure database of healthcare providers who have notified Roxane of completion of training, which will be defined as all training materials were reviewed independently by the healthcare provider.
- ix. Ensure that the REMS materials listed below are available on the Alosetron REMS Program website or by calling the REMS contact center.

The following materials are part of the REMS and are appended:

- REMS Training Kit
 - REMS letter for Healthcare Providers
 - Alosetron REMS Program Prescriber Education Slide Deck
 - Alosetron REMS Program Safety Information Fact Sheet for Prescribers
 - Alosetron REMS Program Patient Education Sheet
 - Prescriber Completion of Alosetron REMS Program Training Form
- Other appended REMS materials:
 - Alosetron REMS Program website Prescriber Section screenshots
 - Alosetron REMS Program website Patients Section screenshots
 - REMS letter for Professional Societies